UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 16, 2023

THERIVA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-12584**	**13-3808303**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(Address of principal executive offices and zip code)

(301) 417-4364
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	TOVX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 7.01. Regulation FD Disclosure.

On February 16, 2023, Theriva Biologics, Inc. (the "Company") issued a press release announcing that the presentation of blinded safety and pharmacokinetic (PK) data from the ongoing Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD). These data will be featured in a poster presentation at 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, being held in Orlando, Florida from February 15-19, 2023.

Cohort 1 of the study enrolled 19 patients who received at least 1 dose of study drug (SYN-004 or Placebo randomized 2:1). Twelve of these patients completed two doses of IV MER to be evaluable towards the study endpoints. While the study is on-going and remains blinded, key findings showcased in the poster presentation (#LBA6) titled "Interim Analysis of SYN-004 Phase 1b/2a Trial in Hematopoietic Cell Transplant (HCT) Recipients" include:

- Adverse events (AEs) and serious adverse events (SAEs) observed in Cohort 1 were typical of those observed in allo-HCT patients and no AEs or SAEs were determined to be related to study drug treatment by the investigators.

- Consistent with previous studies of SYN-004 in healthy volunteers, SYN-004 was not observed in blood samples from the majority of the evaluable patients.

- Meropenem pharmacokinetics were as expected for this patient population.

A copy of the poster titled "Interim Analysis of SYN-004 Phase 1b/2a Trial in Hematopoietic Cell Transplant (HCT) Recipients" is filed as an exhibit to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

Item 8.01. Other Events.

On February 16, 2023, the Company presented blinded safety and pharmacokinetic (PK) data from the ongoing Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD). These data will be featured in a poster presentation at 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, being held in Orlando, Florida from February 15-19, 2023.

Cohort 1 of the study enrolled 19 patients who received at least 1 dose of study drug (SYN-004 or Placebo randomized 2:1). Twelve of these patients completed two doses of IV MER to be evaluable towards the study endpoints. While the study is on-going and remains blinded, key findings showcased in the poster presentation (#LBA6) titled “Interim Analysis of SYN-004 Phase 1b/2a Trial in Hematopoietic Cell Transplant (HCT) Recipients” include:

- Adverse events (AEs) and serious adverse events (SAEs) observed in Cohort 1 were typical of those observed in allo-HCT patients and no AEs or SAEs were determined to be related to study drug treatment by the investigators.

- Consistent with previous studies of SYN-004 in healthy volunteers, SYN-004 was not observed in blood samples from the majority of the evaluable patients.

- Meropenem pharmacokinetics were as expected for this patient population.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Theriva Biologics, Inc., dated February 16, 2023
99.2	Poster titled “Interim Analysis of SYN-004 Phase 1b/2a Trial in Hematopoietic Cell Transplant (HCT) Recipients”
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 16, 2023

THERIVA BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer and Chief Financial Officer